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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,753

07/25/2007

Henrik Arnberg

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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

NOTIFICATION DATE

DELIVERY MODE

03/16/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/599,753	<b>Applicant(s)</b> ARNBERG, HENRIK	
	<b>Examiner</b> GYAN CHANDRA	<b>Art Unit</b> 1646	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 16, 18, 21-26 and 29.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

/Robert Landsman/  
 Primary Examiner, Art Unit 1647

Continuation of 5. Applicant's reply has overcome the following rejection(s): 35 USC 112, first paragraph, written description, 35 USC 112, first paragraph, scope of enablement and 35 USC 112, second paragraph.

Continuation of 11 does not place the application in condition for allowance because:

Claims 17, 19-21, 27, 28, 30 and 31 are cancelled.

Claims 16, 18, 21-26 and 29 are pending.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18, 21-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Grabstein et al (US Patent No. 5,162,111) in view of Grzybowski et al (Int. J. Pharmaceutics 184: 179-187, 1999) and further in view of Sampathkumar (US Patent No. 4,804,530) for the reasons of record in pg. 6-10.

Applicants argue that because they cancelled claim 17, and that the limitations of claim 17 are included in claim 16, therefore, the rejection under 35 USC 103 over Grabstein et al in view of Grzybowski et al is rendered moot. Applicants argue that Grzybowski et al only teach that dressings containing GM-CSF can be prepared but only treat bacterial infection using G-CSF, not GM-CSF and argue that one of skill in the art knows that G-CSF and GM-CSF are distinct proteins. Applicants argue that the antimicrobial effect of rhG-CSF does not necessarily mean that this cytokine will accelerate wound healing. Applicants argue that Grzybowski et al teach that G-CSF is not equivalent to GM-CSF as recited in the instant claims. Applicants argue that the reference Sampathkumar does not teach or suggest a method comprising local administering a composition comprising a therapeutically effective amount of GM-CSF to treat periodontal disease or sinusitis.

Applicants' arguments have been fully considered and they are not persuasive because the limitations of the cancelled claim 17 are included in claim 16, and now the rejection of claim 16, 18, 21-26 are being examined over Grabstein et al. in view of Grzybowski et al and further in view of Sampathkumar. Grabstein et al teach a composition comprising GM-CSF for the treatment of bacterial infection (col. 11, lines 50+, Example 1 and claim 1). Grabstein et al teach making GM-CSF using recombinant technology (col. 8, lines 18+, Example 5 and claim 2). They teach that GM-CSF is efficacious as an anti-infective agent (col. 4, lines 35+). They teach administering a recombinant GM-CSF to a subject suffering from bacterial infection in dosages of about 0.05 to 500 ug/Kg of body wt of the subject per day (col. 5, lines 18+ and Examples 1-2, and 4) or periodically as contemplated in claim 8, which would be equivalent to 30 µg to 30,000 µg for a 60 Kg subject, and thus the teachings of Grabstein et al meet the limitations of claims 22-26. Grzybowski et al do teach preparing dressings containing GM-CSF or G-CSF which is suitable for local administration (page 180, Materials and methods). Grzybowski et al do teach that the art discloses a method for using GM-CSF for treating bacterial infection (see Grabstein et al as applied above, and previously presented, Schneider and Dschner (1998)). Therefore, Grzybowski et al contemplate using GM-CSF for treating bacterial infection. Regarding applicants' arguments that the antimicrobial effect of hG-CSF does not necessarily mean that this cytokine will accelerate wound healing has been fully considered but not persuasive because the features upon which applicant relies (wound healing) are not recited in the rejected claim(s). It is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, regarding applicants' arguments that the reference Sampathkumar does not teach or suggest a method comprising local administering a composition comprising a therapeutically effective amount of GM-CSF to treat periodontal disease or sinusitis have been fully considered but they have not been found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

It is noted to Applicant that claim 29 was rejected under 35 USC 102 because the reference Grabstein et al teach a composition comprising GM-CSF but inadvertently this claim was included along with claims 16, 21-27 which were withdrawn due to the amendments of claim 16. Therefore, the rejection is being reinstated.

Claim 29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Grabstein et al (US Patent No. 5,162,111) for the reasons of record in pg. 9-10 of the office action of 8/2008.